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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,435	02/02/2002	Edward J. Yurkow	RU-0130	9557
26259	7590	05/23/2005	EXAMINER	
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER

1614

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,435

Applicant(s)

YURKOW ET AL.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4-25-05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

The finality of the last Office Action is withdrawn subsequent to the filing of an Information Disclosure Statement on April 25, 2005. Claims 1 and 5 remain under consideration. Support for the amendment to claim 5 appears on page 3 of the specification.

In the last Office Action claims 1 and 5 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention with respect to the recitation "specific redox state". It was asserted clarification remained required because "specific" is a relative term that is not defined by the claims. The specification does not provide a standard for ascertaining the scope of "specific redox state".

Applicants argue the specification teaches at page 5, lines 5-17 and at page 8, line 34, to page 9, line 11, that a specific redox condition is sustained to facilitate the action of the therapeutic agent and the specific redox state is defined by the levels of cellular GSH, MT and other redox-defining molecules that correlate with indicators of tumor differentiation and proliferation.

Applicants' argument is persuasive and the rejection of record under 35 U.S.C. 112, first paragraph, is withdrawn.

Claim 5 was rejected under 35 U.S.C. 102(a) as being anticipated by Obrosova et al., Diabetologia (abstract) in the last Office Action. It was asserted Obrosova teaches a diabetic model wherein a stabilization of lenticular cells that were contacted with the thiol-containing molecule, DL- α -lipoic acid, is demonstrated.

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Applicants argue that an amendment to the claim, wherein *hyperproliferative* cells are now contemplated, distinguishes the claimed subject matter from Obrosova.

Applicants' argument is not persuasive because the abstract of the reference teaches "diabetes-induced changes in lens antioxidant status". It is unclear whether or not such changes are properly "hyperproliferative" changes. Merely excessive growth or rapidly growing lenticular cells would characterize such changes. The rejection of record under 35 U.S.C. 102(a) is maintained.

Applicants' arguments with respect to the rejection of claim 1 in the last Office Action under 35 U.S.C. 102(e) as being anticipated by Demopoulos et al., US 2002/0136763, have been considered but are moot in view of the new ground of rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Rosl et al., U.S. Patent 6,238,659.

Rosl teaches the administration of the sulfhydryl-containing molecule pyrrolidine dithiocarbamate to influence, modulate or stabilize the cellular redox state of viral cells of a papilloma lesion to increase or sensitize the effect of a cytokine, the chemotherapeutic agent. See Example 2, column 2.

No claim is allowed.

Applicants' submission of an Information Disclosure Statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on April 25, 2005 prompted the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire **THREE MONTHS** from the mailing date of this Action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-

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0585. The Examiner can normally be reached Mondays to Fridays from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at telephone number 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack
Phyllis G. Spivack
Primary Examiner
Art Unit 1614

**PHYLLIS SPIVACK
PRIMARY EXAMINER**

May 19, 2005